SEP 1 9 2001

K012165/S1

Nucletron

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Department of Health and Human Services
Center of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

a. Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	7080 Columbia Gateway Drive Columbia, MD 21046-2133
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Lisa Dimmick

b. Device Name:

Trade/Proprietary Name:	Oldelft ThoraScan (internally also known as ThoraScan and Digidelca-T)
Common/Usual Name:	Digital Chest X-ray System
Classification Name:	Stationary X-ray System (90-KPR)
Classification	Class II
CFR Citation	21 CRF 892.1680 Tier 1 submission
Panel	Radiology

c. Legally Marketed Device(s)

Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Digidelca	K980296

d. Description:

ThoraScan is a digital X-ray chest camera based on slot-scan technology and is designed to perform radiographic chest examinations. The detector is comprised of CCD's directly coupled to a cesium iodide scintillator. The digital image is sent through a DICOM network. The ThoraScan consists of a camera stand with detector, tube stand, control unit, x-ray tube, collimator, generator and the OWS (Operators workstation).

e. Intended use

Clinical or mass-chest radiography

f. Summary of technological considerations

The ThoraScan is substantially equivalent to the predicate device (Digidelca). Compared to the Digidelca the slot-scan detector and the control unit have been improved.
The ThoraScan presents no new safety concerns. It will comply with the x-ray requirements of 21CFR 1020.30/31 as well as safety requirements of UL -187, IEC601-1 and collateral standards, as well as the requirements of the Medical Device Directive (93/42/EEC) and the EMC Directive (89/336/EEC).

g. Non-clinical tests

Prototype tests of the detector include a.o. resolution and contrast measurements which are reported in Tab 10 of this application and which show superior results compared to the Digidelca-C.

h. Clinical tests

PA and lateral radiograms were judged by several radiologist and found the digital images had better image quality than the Digidelca-C

i. Conclusions

Nucletron considers the ThoraScan to be equivalent with the predicate device.
The ThoraScan provides radiograms that result in better imaging performance than Digidelca.

28/06/01

Name: Rudolf Scholte
Title: Business Manager
Nucletron B.V.
Veenendaal, The Netherlands

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

Ms. Lisa Cole Dimmick
Director of Regulatory Affairs
Nucletron Corporation
7080 Columbia Gateway Drive
COLUMBIA MD 21046-2133

Re: K012165
Trade/Device Name: Oldelft Thorascan Number 180T
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: II
Product Code: 90 KPR
Dated: August 24, 2001
Received: August 27, 2001

Dear Ms. Dimmick

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K012165

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Statement of intended use

Device Name: Oldelft ThoraScan

Intended Use:
ThoraScan provides the radiologists or pneumologists the ability to acquire chest x-ray images by filmless radiography (digital radiography), based on a CsI/CCD slot scan detector produced by Thomson TE.

The x-ray transmission profile of the chest is converted into an electronic, digital image in real-time. Chest images become available for preview by the x-ray technician on the operator's workstation only seconds after the x-ray exposure.
After acceptance by the tech, digital (DICOM) images can be stored on electronic media, as e.g. CD-ROM, magnetic disk, or be exported to a (DICOM/PACS) network, c.q. clinical review station or to a film printer.

Note: PACS, networks, clinical review stations and (laser-) film printers are not considered part of the Digidelca system for which this application is filed, only external interfaces tot this type of equipment are defined.

Prescription use:
The Nucletron Oldelft ThoraScan is intended to be used for medical procedures on patients to be prescribed and performed by a suitably trained and certified medical professional.

28/6/01

Name:
Title: Business Manager
Nucletron B.V.
Veenendaal, The Netherlands

Date

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012165

Prescription Use ✓